DISCORDANT HARMONIZATION: DID THE EUROPEAN COURT OF JUSTICE INTERPRET THE BIOTECHNOLOGY DIRECTIVE’S EXCLUSIONS TO PATENTABILITY TOO BROADLY IN BRUSTLE V. GREENPEACE?

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Abstract

Stem cell technology offers the hope of treating a variety of diseases for which no effective treatment is currently available. Development of most therapeutic technologies depends on the availability of patent rights, which offer the opportunity to recoup the substantial investment necessary for such inventions. The question of whether human embryonic stem cells (hESCs) are eligible for patent protection raises deep-seated questions of ethics, with compelling moral arguments on both sides. The European Union’s Biotechnology Directive, passed in 1998, excludes from patentability inventions that involve the use of human embryos as contrary to ordre public or morality. Since the enactment of the Directive, decisions from both the European Patent Office (EPO), which is not bound by the Directive, indicated that the EPO would not grant patents on inventions involving hESCs. More recently, the European Court of Justice has given an authoritative interpretation of the Directive confirming that hESC-based inventions are not patentable in EU member states. Analysis of these decisions suggests that these bodies have reached results that are inconsistent with the language and purpose of the Directive.

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Contents

I. Introduction ............................................................................................................................. 3

II. History of the Directive’s Exclusions to Patentability ............................................................ 4
   A. Establishment of the EPO by the EPC ................................................................................. 4
   B. The Biotechnology Directive .............................................................................................. 6

III. Interpretation of Exclusions to Patentability by the EPO .................................................. 9
   A. Incorporation of the Directive’s Exclusions to Patentability into the EPC ...................... 9
   B. Edinburgh Opposition .......................................................................................................... 9
   C. WARF Patent Appeal .......................................................................................................... 12

IV. Interpretation of Exclusions to Patentability by the ECJ in Brustle v. Greenpeace ........ 14
   A. The Opinion of the ECJ ....................................................................................................... 14
   B. Flaws in the ECJ’s Interpretation of Article 6(2)(c) of the Directive ............................. 17
      1. The ECJ’s interpretation of “human embryos” is overinclusive .................................... 17
      2. The ECJ incorrectly equated “for industrial or commercial purposes” with 
         “[susceptible of] industrial application” ............................................................................ 20
      3. The ECJ’s interpretation of “uses . . . for industrial or commercial purposes” is 
         overinclusive .................................................................................................................. 21

V. Conclusion .................................................................................................................................. 22
I. Introduction

The discovery of embryonic stem cells was one of the major biomedical advances in the twentieth century.\(^1\) Embryonic stem cells have the dual capacity to reproduce themselves by dividing and to differentiate into the various specialized cell types that make up mature multicellular organisms.\(^2\) Consequently, isolated embryonic stem cells provide a self-perpetuating source of starting material that can potentially develop into organs and tissues under appropriate conditions.\(^3\) The first isolation of human embryonic stem cells (hESCs) in the late 1990’s offered the hope of regenerative therapy for a host of diseases caused by the loss of function of specific cells or tissues.\(^4\) At the same time, the identification of hESCs raised ethical concerns about the possibility of human cloning and eugenics.

Shortly after the first hESCs were identified, the European Union (EU) acted to address the ethical issues and promote innovation related to hESC technology. In 1998 the European Parliament and Council of the European Union enacted Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (Directive).\(^5\) Article 6 of the Directive provides both general and specific exclusions to patentability of inventions relating to human cloning as contrary to ordre public or morality.\(^6\) The European Patent Office (EPO), which administers the grant of patents under the authority of the European Patent Convention


\(^3\) Id.

\(^4\) Treichel, *supra* note 1, at 462.


\(^6\) Biotechnology Directive, *supra* note 5, at art. 6, 18. Ordre public is commonly translated as “public policy” but has different meanings European countries. For example, ordre public is considered separate from fraud in the United Kingdom but encompasses fraud in France and Germany. http://www.ordrepublic.de/english.php#PublicPolicyFraudOrdrePublic. Consequently, the untranslated term will be used in this paper.
(EPC), took notice of the Directive. Although the EPO has no legal or political ties to the EU, in 1999 the EPO voluntarily incorporated Article 6 verbatim into the EPC Implementing Regulations.7

Over the last decade, institutions within both legal frameworks have addressed whether inventions that employ hESCs are patentable under Article 6. Article 6(2)(c) precludes patenting of inventions involving “uses of human embryos for industrial or commercial purposes.”8 In 2003 and 2008, bodies within the EPO construed this exclusion broadly and ruled that the EPO would not grant patents on inventions that require isolation of hESCs from human embryos. In October 2011, the European Court of Justice (ECJ), the highest court of the European Union (EU), adopted a similarly broad interpretation of Article 6(2)(c) in Brustle v. Greenpeace.9 The ECJ’s interpretation of the Directive effectively forecloses patenting of hESC-related inventions in EU member states, a result that the drafters of the Directive did not intend.10

II. History of the Directive’s Exclusions to Patentability

A. Establishment of the EPO by the EPC

To assess the validity of the ECJ’s interpretation of the Biotechnology Directive’s exclusions to patentability, an understanding of the European patent system is necessary. The first step toward the creation of a Europe-wide patent system was the signing of the EPC in 1973.11 The primary objective of the EPC is “to ensure that [patent] protection may be

8 Biotechnology Directive, supra note 5, at art. 6(2)(c), 18.
obtained in the Contracting States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted.”12 Toward that end, the EPC established the EPO. To date, thirty-eight countries have acceded to the EPC.13

The EPC has a narrowly circumscribed scope that only concerns the process by which patents are granted.14 Although the EPO refers to an approved application as a “European patent,” the document does not confer rights as such. Rather, approval of a patent application by the EPO grants an applicant the right to obtain a national patent in any EPC contracting state.15 In addition, the EPC leaves the determination of substantive rights of issued patents to contracting states.16 Thus, the EPC does not require member states to bring their national patent laws into conformity with the EPC, although most have done so.17 Moreover, does not foreclose an applicant from seeking a national patent directly from a member state.18

Significantly, the EPC is separate from the series of treaties that gave rise to the EU in 1993. In contrast to the EPC, the Treaties of the European Union create broad economic and political ties among EU member states.19 Although all twenty-seven signatories to the EU are members of the EPC, eleven EPC contracting states are not in the EU.20 Due to their separate jurisdictions, bodies within the EU and EPC have no legal relationship. Consequently, institutions of the EU, such as the ECJ, lack the authority to review EPO

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14 PLOMER, supra note 12, at 88.
15 GOWERS REVIEW OF INTELLECTUAL PROPERTY ¶ 1.34, 18 (Her Majesty’s Stationery Office, UK, 2006).
16 PLOMER, supra note 12, at 88.
17 Id.
18 However, eleven EPC contracting states have ceased issuing patents via the national route and only issue patents granted by the EPO.
decisions.\(^{21}\) Within EU member states, however, EU law has supremacy over national law according to ECJ doctrine.\(^ {22}\) The disjunction between the EU and EPC places an applicant for a patent from the EPO in a potential position of double jeopardy within EU member states. First, he must prove that his invention is patentable under the requirements of the EPO. Then, if the patent is challenged in an EU member state, he must re-assert the validity of the patent under a non-identical standard of patentability.\(^ {23}\)

**B. THE BIOTECHNOLOGY DIRECTIVE**

The Biotechnology Directive sought to promote the life sciences industry by unifying substantive European patent laws that lay beyond the reach of the EPC. Although the Biotechnology Directive was enacted in 1998, its origins precede the formation of the EU. In 1988, the European Commission, believing that EPC would not foster a robust biotechnology industry, proposed the first draft of the Biotechnology Directive.\(^ {24}\) The European Commission acknowledged that “genetic engineering, research and development require a considerable amount of high-risk investment and . . . only adequate legal protection can make them profitable.”\(^ {25}\) Differences in patent protection of biotechnological inventions between European nations create trade barriers within the European market.\(^ {26}\) In the absence of a uniform system of protection, European patent laws could become further fragmented and exacerbate trade barriers in the internal market.\(^ {27}\) The Biotechnology Directive therefore


\(^{23}\) Superficially, this “double jeopardy” scenario may seem no different from the biphasic patent process in other jurisdictions, such as the United States, in which a patent is granted by an executive body and then reviewed upon challenge by the judicial branch. The key difference is that in national jurisdictions like the United States, the executive and judicial branches may differ in their interpretations of the same law, whereas the EPO and ECJ, being jurisdictionally distinct, must interpret different law.


\(^{26}\) Id. at rec. 5, 13.

\(^{27}\) Id. at recs. 6-7, 13.
sought to provide “effective and harmonized [patent] protection throughout the Member States . . . in order to maintain and encourage investment in the field of biotechnology.”

Although the original motivations for the Directive were economic, issues of ethics and morality also assumed importance during the drafting process. Article 5 of the Directive prohibits the patenting of the human body but permits patenting of isolated elements thereof:

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Article 6 states that inventions contrary to ordre public or morality are not patentable. During drafting of the Directive, a 1997 amendment first introduced the term “human embryos” into this morality clause. The drafting language proposed a ban on patenting of “[m]ethods in which human embryos are used.” In 1998 the Council of the European Union altered the wording to exclude from patenting only certain uses of human embryos. The Council’s wording was retained in Article 6 of the enacted Directive, which reads in relevant part:

28 Id. at rec. 3, 13.
29 Id. at art. 5, 18.
Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

   ...  
   (c) uses of human embryos for industrial or commercial purposes;33

Article 6(1) thus codifies a general principle that gives member states discretion to exclude subject matter from patentability on moral grounds.34 In contrast, Article 6(2)(c) provides a specific moral exclusion to patentability under which member states have no flexibility.35

Enactment of the Directive created an obligation for member states to adopt national laws to comply with the Directive by July 30, 2000.36 Pursuant to the Treaty on the Functioning of the European Union, member states have latitude in the manner of transposition as long as it achieves the results of the Directive.37 The disagreements that stalled passage of the Directive for a decade manifested themselves again as delays in its implementation. Only seven member states had implemented the Directive by its due date, and EU-wide transposition was not completed until 2006.38 The majority of EU member states have adopted the language of Article 6 of the Directive verbatim into national laws, but some have used altered wordings.39

33 Biotechnology Directive, supra note 5, at art. 6, 18
34 PLOMER, supra note 12, at 63-65.
35 Id.
39 PLOMER, supra note 12, at 24-25.
III. Interpretation of Exclusions to Patentability by the EPO

A. INCORPORATION OF THE DIRECTIVE’S EXCLUSIONS TO PATENTABILITY INTO THE EPC

To promote consistency in the patenting of biotechnology inventions within Europe, the exact language of the Directive’s Article 6 was incorporated into the EPC in 1999.\(^{40}\) Rule 23b of the EPC provides guidance on how the EPO (and its constituent boards of appeal) should interpret the Article 6-derived language in reviewing patents and applications.\(^{41}\) The relevant provisions of the EPC itself, interpreted in accordance with the biotechnology provisions, should be the primary source of authority.\(^{42}\) The tools for this task include EPC rules, the Vienna Convention governing the interpretation of treaties, and the EPO’s own jurisprudence.\(^{43}\) However, Rule 23b also allows the use of the Directive “as a supplementary means of interpretation.”\(^{44}\)

In two cases, bodies of the EPO have addressed the application of EPC Rule 28(c), which corresponds to Article 6(2)(c) of the Directive, to inventions involving hESCs.\(^{45}\) In both cases, boards of appeal interpreted the EPC’s specific exclusion of “uses of human embryos for industrial or commercial purposes” broadly to find the inventions unpatentable. Although these decisions are not binding on the ECJ, they informed the ECJ’s decision in *Brustle v. Greenpeace*. A review of these cases thus sheds light on the ECJ’s reasoning in *Brustle* and the general trend of expansion in the exclusions to patentability related to hESC.

B. EDINBURGH OPPOSITION


\(^{41}\) European Patent Convention, *supra* note 11, rule 23b.

\(^{42}\) *Id.*

\(^{43}\) PLOMER, *supra* note 12, at 98.

\(^{44}\) European Patent Convention, *supra* note 11, rule 23b.

\(^{45}\) Article 6(2)(c) of the Biotechnology Directive was originally transposed to the EPC as Rule 23d(c) and subsequently re-codified as Rule 28(c). Although the rule existed as Rule 23d(c) at the time of the Edinburgh case discussed *infra*, the rule will be referred to as Rule 28(c) in this paper for consistency.
The first interpretation of EPC Rule 28(c) as it applies to inventions related to hESCs came from the Opposition Division (OD) of the EPO in 2003. The EPO had granted the University of Edinburgh a patent for methods of isolating “animal stem cells.” The broad language of the claims encompassed methods of isolating hESCs, which necessarily entail the destruction of human embryos. Consequently, fourteen parties opposed the Edinburgh patent as violating Article 53(a) of the EPC, the transposition of Article 6(1) of the Directive. According to the OD, validity of the patent claims under Article 53(a) turned on whether Rule 28(c) was interpreted narrowly or broadly. A narrow reading of the ban on patentability of “uses of human embryos for industrial or commercial purposes” would only prohibit patenting of human embryos as such. Conversely, a broad construction of the ban would also foreclose patenting of methods in which the destruction of human embryos was ancillary to the isolation of hESCs.

The OD relied heavily on the Directive in favoring a broad interpretation of Rule 28(c). In a curious reading of Rule 23b, the OD held that the rule “mandates... use [of the Directive] as a supplementary means of interpretation.” The OD focused on a comparison

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49 The EPC permits third parties to oppose the validity of patent within nine months of issuance. European Patent Convention, supra note 11, at art. 99(1). All fourteen opponents challenged the patent under Article 53(a); some opposed the patent on additional grounds.

50 European Patent Convention, supra note 11, at art. 53(a). At the time of the Edinburgh case, Article 53(a) barred patentability of “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality . . . .” It was subsequently amended to prohibit patenting of “inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality . . . .” The change in wording has not affected the EPO’s application of Article 53(a) to inventions involving hESCs. WARF Patent Appeal, supra note 21, ¶ 30, at 329.


52 Id.

53 Id.

54 Id. (emphasis added).
of the language of Articles 5(1) and 6(2)(c) of the Directive. Because Article 5(1) precludes patenting of “[t]he human body, at the various stages of its formation and development,” it necessarily bars patenting of human embryos as such. A narrow reading of Article 6(2)(c) would render this provision superfluous. Thus, Article 6(2)(c) (and Rule 28(c) of the EPC) must be read broadly to avoid redundancy. From this analysis, the OD concluded that Rule 28(c) “encompass[es] not only the industrial or commercial use of human embryos but also the human ES cells retrieved therefrom by destruction of human embryos.”

In its decision, the OD dismissed two sources of guidance that cast doubt on such a categorical ban on the patentability of hESCs. First, the OD found “[t]he fact that Rule [28(c)] refers to ‘uses’ for ‘industrial or commercial purposes’ is not of relevance in the given context.” According to the OD, an “industrial or commercial purpose” for an invention is implied in every patent application. The OD made no mention that this restriction was added during the drafting of the Directive, suggesting a legislative intent to exclude only certain purposes. Second, the OD rejected Opinion 16 from the European Group on Ethics in Science and New Technologies (EGE), which concludes that hESCs may constitute patentable subject matter under certain conditions. Article 7 of the Directive states that the EGE evaluates ethical aspects of biotechnology, and Opinion 16 had been

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55 Id. at 22. Article 5(1) of the Biotechnology Directive had been transposed to the EPC as Rule 23e(1) at the time of the decision and has since been re-codified as Rule 29.

56 Id.

57 Id.

58 Id.

59 Id.

60 Id.

61 See Common Position, supra note 32, at 17.

requested by the European Commission. Opinions from the EGE are not binding on either the EPO or ECJ but may be used to guide decisions on patentability. Nonetheless, the OD found Opinion 16 unpersuasive due to its use of concepts that are vague or lack counterparts in patent law.

C. WARF PATENT APPEAL

In 2008 the Enlarged Board of Appeal (EBA), the highest authority of the EPO, interpreted Rule 28(c) in the context of inventions relating to hESCs. The EPO had denied a patent application from the Wisconsin Research Alumni Foundation (WARF) that claimed cultures of primate embryonic stem cells, including hESCs. The specification of the application taught that spare embryos from in vitro fertilization therapy were a necessary starting material for hESC cultures. The applicants appealed the rejection from the Technical Board of Appeals (TBA) of the EPO on several grounds, and the TBA submitted four questions for review by the EBA. Among them was a question present but not squarely addressed in Edinburgh:

“[D]oes Rule [28(c)] forbid the patenting of claims directed to products which . . . at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?”

In answering the question in the affirmative, the EBA rejected a series of arguments by the applicant for why Rule 28(c) did not apply to its invention. As did the OD in

63 Biotechnology Directive, supra note 5, at art. 7, 19.
64 PLOMER, supra note 12, at 117-28.
65 Id. at 118.
68 Id.
69 WARF Patent Appeal, supra note 21, ¶ 14, at 308.
Edinburgh, the EBA in the WARF used the Directive to support its broad interpretation of the language of Rule 28(c). The applicant first argued that the term “embryo,” as understood in the medical field, applies only to embryos at least fourteen days old.\(^{70}\) In rejecting this argument, the EBA noted that the definition of “embryo” is absent from both the Directive and the EPC. The EBA found the absence of a definition to manifest a legislative intent to avoid giving “embryo” a restrictive meaning.\(^{71}\) The EBA concluded that “what is an embryo is a question of fact in the context of any particular patent application.”\(^{72}\) The applicant also contended that the invention did not involve the use of human embryos “for industrial or commercial purposes” under Rule 28(c).\(^{73}\) The applicant cited the addition of this phrase during drafting of Article 6(2)(c) of the Directive as evidence of legislative intent to narrow the exclusion to patentability to certain uses.\(^{74}\) The EBA rejected this argument by acknowledging the addition of Recital 42 of the Directive during its legislative history.\(^{75}\)

Recital 42

Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;\(^{76}\)

According to the EBA, Recital 42 indicates that “patentability was only considered if the invention was to the benefit of the embryo itself.”\(^{77}\) Thus, the EBA concluded that Recital 42

\(^{70}\) Id. ¶ 19, at 325.
\(^{71}\) Id. ¶ 20, at 325-26.
\(^{72}\) Id. ¶ 20, at 326
\(^{73}\) Id. ¶ 24, at 327
\(^{74}\) Id. ¶ 26, at 327-28.
\(^{75}\) Id. ¶ 27, at 328.
\(^{76}\) Biotechnology Directive, supra note 5, at rec. 42, 16.
\(^{77}\) WARF Patent Appeal, supra note 21, ¶ 27, at 328 (emphasis added).
supports its view that the invention’s uses of human embryos were “for industrial or commercial purposes.” 78

IV. Interpretation of Exclusions to Patentability by the ECJ in Brustle v. Greenpeace

A. The Opinion of the ECJ

The ECJ recently interpreted Article 6(2)(c) of the Directive as it applies to inventions involving hESCs in Brustle v. Greenpeace. Although the ethical issues and legal conclusions in Brustle were similar to those in Edinburgh and WARF, Brustle is nonetheless a landmark decision. Whereas interpretations of the Directive by the EPO may serve as a beacon to the public, final authority on the Directive lies with the ECJ. Thus, the first decision by the EU’s highest court on the patenting of inventions related to hESCs under on Article (6)(2)(c) is significant for two reasons. First, for patents issued by the EPO, national laws govern substantive rights. For EU member states, national patent laws must be in conformity with the Directive, and the ECJ’s interpretations of the Directive are binding. 79 Therefore, the ECJ is the court of last resort for determining the scope of patent rights in EU countries. Second, the authority of the EPO to grant patents is non-exclusive, and patents issued directly by national offices are beyond the reach of the EPO. 80 Consequently, only the ECJ can adjudicate EU-wide standards for patentability.

The basic features of the disputed patent in Brustle were similar to those in the Edinburgh and WARF. At issue was Brustle’s German patent that claimed methods for generating neural tissues from hESCs. 81 The patent did not disclose a method for isolating hESCs; however, human embryos at the blastocyst stage were the only source of hESCs

78 Id. ¶ 31, at 329.
79 See supra note 22.
80 See supra text accompanying note 18.
available as of the filing date of the application.\footnote*{82} Germany had incorporated Article 6(2)(c) verbatim into its national patent law, and Greenpeace challenged the validity of the patent under this clause in the German court system. The German Federal Court of Justice (FCJ) noted that the validity of the patent under German patent law turned on the interpretation of Article 6(2)(c) of the Directive.\footnote*{83} The FCJ therefore stayed proceedings and referred three questions on the construction of Article 6(2)(c) to the ECJ.\footnote*{84}

The first question referred to the ECJ concerned the meaning of “human embryos” in Article 6(2)(c) of the Directive:

1. What is meant by the term “human embryos” in Article 6(2)(c) of [the Directive]?
   (a) Does it include all stages of the development of human life, beginning with the fertilization of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?
   (b) Are the following organisms also included:
      - unfertilized human ova into which a cell nucleus from a mature human cell has been transplanted;
      - unfertilized human ova whose division and further development have been stimulated by parthenogenesis?
   (c) Are stem cells obtained from human embryos at the blastocyst stage also included?\footnote*{85}

In addressing this question, the ECJ emphasized that a provision in EU law that does not reference a national law “must normally be given an independent and uniform interpretation throughout the European Union.”\footnote*{86} The ECJ further noted that it must not “broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive.”\footnote*{87} Ultimately, the ECJ concluded that parts (a) and (b) of the

\footnote*{83} Id. ¶ 20.
\footnote*{84} Id. ¶ 23.
\footnote*{85} Id..
\footnote*{86} Id. ¶ 25.
\footnote*{87} Id. ¶ 30.
first question should be answered in the affirmative. On part (c), however, the ECJ held that “it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive.”

The second question before the ECJ focused on the meaning of the expression “uses of human embryos for industrial or commercial purposes.” In particular, the ECJ was asked whether the expression “include[s] any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?” The ECJ held that Article 6(2)(c) does cover the use of human embryos for scientific research and therefore excludes patenting of inventions that rely on such uses. In its analysis, the ECJ used lines of reasoning similar to those employed in *Edinburgh* and *WARF* to address the same question in the context of the EPC. First, the ECJ noted that “the grant of a patent implies, in principle, its industrial or commercial application.” This reasoning is similar to approach of the OD *Edinburgh*. Second, the ECJ found Recital 42 of the Directive persuasive in distinguishing between industrial or commercial uses of embryos and therapeutic or diagnostic purposes that benefit the embryo. The ECJ noted that this interpretation was identical to that of EBA in *WARF*. The ECJ also cited Recital 14 of the Directive to support its position: “a patent for an invention ‘entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes’ . . . .”

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88 *Id.* ¶ 38.
89 *Id.*
90 *Id.* ¶ 23.
91 *Id.*
92 *Id.* ¶ 39.
93 *Id.* ¶ 41.
94 *Id.* ¶ 44.
95 *Id.* ¶ 42 (quoting Biotechnology Directive, *supra* note 5, at rec. 14, 14).
The third question to the ECJ was whether Article 6(2)(c) precludes patenting of an invention that necessitates the use of human embryos as a precondition to perform the invention. The ECJ cited two clauses that had supported its answer to the second question in finding that Article 6(2)(c) excludes such inventions from patentability. First, the ECJ noted that Recital 16 states that “patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.” 96 Second, the ECJ held that prohibition of patenting of the human body under Article 5(1) extends to “implementation of the invention.” 97 In addition, the ECJ noted that its conclusion on this issue was also consistent with the decision of the EBA in WARF.

B. FLAWS IN THE ECJ’S INTERPRETATION OF ARTICLE 6(2)(C) OF THE DIRECTIVE

1. The ECJ’s interpretation of “human embryos” is overinclusive. The ECJ’s legal analysis in Brustle contains several flaws that undermine the soundness of the court’s conclusions. The ECJ’s response to the first question is illustrative. The first question focused on the meaning of “human embryos” in Article 6(2)(c). In grappling with the issue, the ECJ sought to give the term “an independent and uniform interpretation throughout the European Union.” 98 The ECJ achieved that objective by answering parts (a) and (b) of the first question affirmatively. Specifically, the ECJ held that any fertilized ovum or non-fertilized ovum that either has received a transplanted nucleus or has been stimulated to divide by parthenogenesis is a “human embryo.” 99 For part (c), however, the Court declined to decide “whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo.’” 100 Instead, the ECJ left the question “for the referring court

96 Id. ¶ 32 (quoting Biotechnology Directive, supra note 5, at rec. 16, 14).
97 Id. ¶ 49.
98 Id. ¶ 25.
99 Id. ¶ 38.
100 Id.
to ascertain, in the light of scientific developments.”\textsuperscript{101} Both the reasoning and holding with regard to part (c) are problematic.

First, by refusing to decide whether hESCs isolated from blastocysts are “human embryos,” the ECJ failed to give the term a “uniform interpretation throughout the European Union.” According to the ECJ, whether an isolated hESC constitutes a “human embryo” remains a question for national courts. Member states, however, are likely to reach divergent answers. Given the invention of the patent at issue, the crux of the first question lay in the proper categorization of isolated hESCs under Article 6(2)(c). By sidestepping the issue, the ECJ has impeded, rather than promoted, harmonization of EU patent laws on protection of inventions related to hESCs.

Second, the ECJ’s deferral of part (c) was inappropriate because the guidance needed to answer that part of the question lies in the Directive itself. Article 5 creates a dividing line of patentability. “The human body, at various stages of its formation and development” cannot be patented.\textsuperscript{102} By contrast, “[a]n element isolated from the human body or otherwise produced by means of a technical process . . . may constitute a patentable invention.”\textsuperscript{103} Thus, Article 5 excludes “stem cells obtained from human embryos at the blastocyst stage” from patentability only if they have the potential to become human bodies. The United Kingdom Intellectual Property Office (UKIPO) adopts this interpretation of the Directive to decide whether inventions involving hESCs are patentable subject matter under the Directive.\textsuperscript{104}

Although the ECJ instructed the referring court to decide part (c) “in light of scientific developments,” the ECJ could readily have done so itself.\textsuperscript{105} Development biologists have

\textsuperscript{101} Id.
\textsuperscript{102} Biotechnology Directive, supra note 5, at art. 5(1), 18
\textsuperscript{103} Id. at art. 5(2), 18.
\textsuperscript{104} UNITED KINGDOM INTELLECTUAL PROPERTY OFFICE, INVENTIONS INVOLVING HUMAN EMBRYONIC STEM CELLS, http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells.htm (last visited Jan. 4, 2012) [hereinafter UKIPO hESC GUIDELINES].
\textsuperscript{105} Brustle v. Greenpeace, ¶ 23.
established that stem cells at different stages at embryonic development vary in their capacity to differentiate into specialized cell types.\footnote{Mitalipov & Wolf, supra note 2.} Totipotent stem cells can produce all the differentiated cell types in a mature organism, whereas stem cells with lesser potency, e.g., pluripotency, cannot.\footnote{Id.} Embryonic stem cells at the blastocyst stage are pluripotent and therefore do not have the potential to become human bodies.\footnote{Id.} Consequently, inventions involving hESCs isolated from blastocysts do not fall within the exclusion to patentability in Article 5(1) and are \textit{prima facie} patentable subject matter under Article 5(2). Thus, “stem cells obtained from human embryos at the blastocyst stage” are not “human embryos” under Article 6(2)(c). The UKIPO uses the distinction between totipotency and pluripotency to define the boundary of patentability for inventions involving hESCs under the Directive.\footnote{UKIPO hESC GUIDELINES, supra note 104.}

Finally, the ECJ foreclosed the possibility that inventions involving hESCs isolated from blastocysts may be patentable by its answer to the third question. Ostensibly, the ECJ’s deferral to the referring court in part (c) appears to leave the question of patentability of such hESCs to national patent laws. Closer examination, however, reveals that this deferral to national authority is moot. Isolation of stem cells from human blastocysts necessarily entails the destruction of the embryo. According to the ECJ’s answer to the third question, the Article (6)(2)(c) exclusion encompasses “the implementation of [an] invention [that] requires the destruction of human embryos.”\footnote{Case C-34/10, Brustle v. Greenpeace, ¶ 49 (2011), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CJ0034:EN:HTML.} An invention involving isolation of hESCs from blastocysts would be therefore excluded from patentability due to the means by which the cells were obtained. Thus, a member state’s decision on whether blastocyst-derived hESCs are patentable \textit{per se} because they are not “human embryos” is immaterial for protecting such inventions. According to the ECJ’s holding, only inventions involving hESCs obtained from
pre-existing cell lines are eligible for patent protection. This drastically limits the utility of stem cell technology and undermines the original purpose of the Directive.

2. The ECJ incorrectly equated “for industrial or commercial purposes” with “[susceptible of] industrial application”. The ECJ’s answer to the second question in Brustle is also deficient due to the court’s facile interpretation of the phrase “for industrial or commercial purposes.” First, the ECJ conflated “industrial or commercial application” of an invention with uses of the invention “for industrial or commercial purpose.” Although these phrases have similar meanings in ordinary parlance, they represent distinct elements of patent law. An invention must be “susceptible of an industrial application” to be patentable under the EPC.111 Thus, having “industrial application” is a technical requirement of patentability.112 The use of this phrase at several points in the Directive reflects an understanding that the phrase has an identical meaning in the context of the directive.113 By contrast, “for industrial or commercial purposes” is original language of the Directive. Whereas the EPC governs the process of granting patents, the Directive defines the scope of patent rights as discussed supra part II.B.

Several sources suggest that the ECJ incorrectly treated the phrases “industrial or commercial application” and “for industrial or commercial purposes” as having equivalent meanings. First, Article 57 of the EPC states that “[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”114 EPO guidelines indicate that “[EPC] Article 57 excludes from patentability very few ‘inventions’ which are not already excluded by the list in [EPC] Article 52(2).”115 These sources support an expansive interpretation of the phrase “industrial

111 European Patent Convention, supra note 11, at art. 52(1).
112 PLOMER, supra note 12, at 74.
113 See, e.g., Biotechnology Directive, supra note 5, at recs. 20-24, 15.
114 European Patent Convention, supra note 11, at art. 57.
application.” An equally expansive interpretation of “for industrial or commercial purposes” in the Directive would therefore be ineffecual at defining the scope of patent rights generally. Second, the legislative history of the Directive supports a narrower interpretation of “for commercial or industrial purposes” in Article 6(2)(c) specifically. As discussed supra part II.B, the Council of the European Union added the phrase during drafting of the Directive to limit the exclusion to certain uses of human embryos.116 Because only inventions with “industrial applications” are patentable, the Council’s modification would not narrow the exclusion unless the two phrases have different meanings. By equating “industrial or commercial application” with “for industrial or commercial purposes,” the ECJ has rendered the Council’s amendment superfluous.

Recital 14 provides further support that the two phrases have distinct meanings. The ECJ quoted a brief excerpt of Recital 14 to buttress its interpretation of “for industrial or commercial purposes.”117 Viewed in context, however, the passage admits of a different construction. The first “whereas” clause of Recital 14 in its entirety states that “[w]hereas a patent for invention does not authorize the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes . . . .”118 Recital 14 thus reflects a clear recognition that satisfying the requirements for obtaining a patent is not sufficient to allow the patent holder to “implement” the invention. The former requires an invention “susceptible of industrial application,” whereas the latter encompasses using the invention “for industrial or commercial purposes.”119

3. The ECJ’s interpretation of “uses . . . for industrial or commercial purposes” is overinclusive. Another flaw in the ECJ’s analysis of the second question is that the court interpreted “uses . . . for industrial or commercial purposes” too broadly. Recital 42 of the

116 Common Position, supra note 32, at 17.
119 European Patent Convention, supra note 11, at art. 52(1).
Directive specifies that the exclusion to patentability “does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it.”\textsuperscript{120} The ECJ therefore concluded that “only use[s] for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it [are] patentable.”\textsuperscript{121} Neither the Directive nor the ECJ, however, gives any indication that the list of patentable uses in Recital is exhaustive. Nor does the ECJ provide reason to conclude that Recital 42, quoted in its entirety \textit{supra} part II.C, lists the entire universe of possible uses of human embryos. Absent these, Recital 42 should be viewed as indicating two sets of uses of human embryos, one potentially patentable and the other not, among many. For example, the United Kingdom allows patenting of inventions involving therapeutic uses of human embryos that benefit the public, even if they are harmful to the embryo.\textsuperscript{122} This interpretive approach better comports with the general principle that exemptions should be construed narrowly.\textsuperscript{123} The analysis proposed here does not preclude a finding that the invention of the Brustle patent involves “uses of human embryos for industrial or commercial purposes” under Article 6(2)(c); it does, however, cast doubt on the basis of the ECJ’s conclusion that the invention does involve such uses.

\textbf{V. Conclusion}

The primary purpose of the Directive is to foster the European biotechnology industry. Development of therapeutic technologies through the use of hESCs is a critical focus of this industry. Patent rights are essential to secure the investment necessary to develop such technologies, and a uniform system of patent protection is necessary to promote

\begin{footnotesize}
\textsuperscript{120} Biotechnology Directive, \textit{supra} note 5, at rec. 42, 16.
\textsuperscript{121} Brustle v. Greenpeace, ¶ 46 (emphasis added).
\textsuperscript{123} \textsc{Plomer}, \textit{supra} note 12, at 116-17.
\end{footnotesize}
the function of internal European markets. The Directive seeks to harmonize and clarify patent laws among EU member states to strengthen the industry.

Despite these goals, the Directive has made Europe less hospitable to the development of hESC technologies due to its morality exclusions. In particular, the exclusion to patentability of “uses of human embryos for industrial or commercial purposes” has created a barrier to patenting inventions involving hESCs. The Directive is binding on EU member states; incorporation of the exclusions to patentability into the EPC made them mandatory for the EPO as well. Over the last decade, EPO decisions giving the morality exclusions broad interpretations have foreclosed the procurement of patents on many hESC-related inventions via the unified EPC system. The ECJ’s recent adoption of a similarly broad interpretation of the morality exclusions in Brustle precludes patentability of these hESC-based inventions altogether in EU member states. Ultimately, these broad interpretations of the morality exclusions will hurt both the economy and health care of Europe as the development of hESC technologies atrophies. As the long-term consequences of these decisions transpire, the EU may find that implementation of the Directive has contravened its original purpose.